

### **III. REMARKS**

Applicants request consideration on the merits of the above-referenced patent application.

#### **A. Amendments to the Specification**

A new descriptive title was added for further clarification. The brief description of the drawings section was titled, and the description of Figure 3 was amended to describe Figure 3 as Figure 3A and Figure 3B for further clarity.

#### **B. Amendments to the Claims**

Claims 1 and 3-20 are pending. Claims 2 and 25 have been cancelled without prejudice to Applicants' right to file divisional applications directed to the subject matter thereof. Claim 1 has been amended to include the phrase "isolated," support for which can be found on page 6, line 25. Claim 1 has also been amended to include the phrase "consisting essentially of the AMPDA catalytic domain", support for which can be found on page 5, line 5. Claims 12 and 13 have been amended to include reference to Seq. ID No. 2.

#### **C. Information Disclosure Statement**

A Supplemental IDS is submitted herewith. The Office states that the information disclosure statement filed on June 24, 2002, failed to comply with 37 C.F.R. §1.98(a)(2) as follows:

*a) Anderson et al. - no copy was provided.* Applicants are submitting a copy of the Anderson et al. reference with the attached supplemental IDS.

*b) Nakamura et al. - the citation was incorrect.* Applicants have corrected the Nakamura citation, which is now cited as Hehre *et al.*

#### **D. Sequence Listing**

*a) The Sequence Listing of June 6, 2002 was objected to as not fully complying with the requirement of 37 C.F.R. §1.821 through 1.825 because the statement under 37 C.F.R. §1.821 did not provide a statement that the content of the paper and CRF copies filed on June 6, 2002 included no new matter. A new statement under 37 C.F.R. §1.821 providing that the content of the paper and CRF copies include no new matter is submitted herewith.*

#### **E. Specification**

The Office objected to the specification as follows:

*a) The title was objected to as not being descriptive.* A new title, "Tetragonal Protein Crystals of AMP Deaminase," has been provided. Applicants submit that the new title is clearly indicative of the invention to which the elected claims are drawn.

*b) The specification contained blank pages.* Applicants confirm that no information is missing. These pages were left unintentionally blank.

*c) The brief description of the drawings lacked a section heading, and Figure 3 allegedly lacked clarity.* Applicants have amended the specification to include a heading for the brief description of the drawings. Figure 3 has been described as Figure 3A and Figure 3B for further clarity.

## **F. Claim Rejections**

### *a) Rejections under 35 U.S.C. § 112, second paragraph*

Amended claims 12 and 13 are definite

On page 4 of the Office Action, the Office rejected Claims 12 and 13 for alleged indefiniteness. Applicants have amended Claims 12 and 13 to include a specific Seq ID No (Seq ID No. 2). Therefore, the residues of the claims are identified according to a specific sequence, and the claims are definite. Applicants respectfully request that the rejection be withdrawn.

### *b) Rejections under 35 U.S.C. § 112, first paragraph*

1. On page 5 of the Office Action, the Office rejected Claims 1-20 for allegedly containing inadequate written description. The Office states that the common structural characteristics of species that define said genera are not described. Applicants respectfully disagree. The common structural characteristics of the genus are 1) isolated AMP protein crystal and 2) *tetragonal shape*. The shape of the crystal is sufficient to distinguish it from other AMP crystals. Therefore, there is sufficient written description, and Applicants request that the rejection be withdrawn.

2. On page 5 of the Office Action, the Office rejected Claim 25 for allegedly containing inadequate written description. Claim 25 has been cancelled without prejudice. Therefore, Applicants request that the rejection be withdrawn.

3. On page 8 of the Office Action, the Office rejected Claims 1-20 for allegedly failing to provide enablement for any AMP deaminase crystal. Applicants submit that amended claims 1 and 3-10 are enabled. Amended claims are directed to a crystal of essentially the catalytic domain of AMP deaminase. This domain is highly conserved (see, for example, page 2 of the specification), and therefore one of ordinary skill in the art would be able to use the guidance of the specification (in particular, pages 13-14) to crystallize this protein without undue experimentation.

*c) Rejections under 35 U.S.C. § 101*

1. On page 11 of the Office Action, the Office rejected Claims 1-20 and 25 for allegedly lacking patentable utility. The Office acknowledges that the specification teaches the usefulness of studying the structure of AMP deaminase using the crystalline form of the protein, but states that there is no specific, substantial and credible utility for AMP itself. Applicants respectfully disagree. Inhibitors of AMP deaminase are known in the art to have specific, substantial and credible utilities. For instance, UK-384,858 (a diazepam derivative) is described in the present application as an AMPDA inhibitor, and is described in WO 94/19200 (see page 3 of the present specification). Several diazepam derivatives which were shown to be AMPDA inhibitors described in WO 94/19200 were successfully used in *in vivo* models to treat ischemic rat hearts, maximal electroshock seizures in rats, ischemic brain injury in rats, myocardial function following ischemia/reperfusion injury in rabbits and pigs, left ventricular function following myocardial ischemia in rabbits and pigs, arterial thrombus development in rabbits, dogs and rats, and myocardial infarct size in rabbits. Applicants therefore submit that AMPDA has several specific, substantial and credible utilities (namely, for use to develop inhibitors which treat the myriad of conditions described above), and request that the rejection be withdrawn.

2. On page 12 of the Office Action, the Office rejected Claims 1-20 as allegedly being directed to non-statutory subject matter. Applicants have amended claim 1 to include the phrase "isolated." Therefore, Applicants request that the rejection be withdrawn.

*d) Rejections under 35 U.S.C. § 102*

1. On page 13 of the Office Action, the Office rejected Claim 25 as allegedly being anticipated by Smiley *et al.* Claim 25 has been cancelled without prejudice. Therefore, Applicants request that the rejection be withdrawn.

2. On page 13 of the Office Action, the Office rejected Claim 25 as allegedly being anticipated by GenBank Accession Number I39444. Claim 25 has been cancelled without prejudice. Therefore, Applicants request that the rejection be withdrawn.

In view of the foregoing amendments, it is respectfully submitted that all claims now active in the present application are in condition for allowance. Therefore, passage of the application and claims to issue is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rachel A. Polster". The signature is fluid and cursive, with the first name "Rachel" being more prominent.

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